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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,530	09/18/2006	Janel Birk	18006 PCT US (INA)	4476

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EXAMINER	
STRANSKY, KATRINA M	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
01/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/593,530	BIRK ET AL.	
	Examiner	Art Unit	
	KATRINA STRANSKY	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *5 and 21-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-20 and 35-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Garay et al, US Patent No. 4,925,446.

3. Regarding claim 1, Garay et al. disclose a gastric balloon (26) comprising: a shell (27); a receiver formed in said shell (Portion of shell that receives tubing 12, see Fig. 5) having a recessed region in the shell (28, Fig. 5); a valve (21) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (12) in fluid communication with the shell house in said receiver and extendable from the stomach of a patient to the mouth of the patient (See Col. 3, lines 1-9), wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (Col, 3, lines 1-9). (See Fig. 5).

4. Regarding claim 4, Garay et al. disclose that the retractable tubing is fluidly connected to the shell via an interface (Portion of shell that receives tubing 12, see Fig. 5).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-3 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al in view of Mouri et al, US Patent No. 6,074,378.

7. Regarding claims 2-3 and 10, Garay et al disclose the claimed invention except for the retractable tubing is formed in one or more spirals or in a coil. However, Mouri et al disclose a self retaining catheter (10) comprising a catheter body (11) having a lumen and made of a shape memory material (col. 5, lines 52-55). The catheter body (11) has a shape memory coil wire (14) buried inside of it (col. 5, lines 66-67 and col. 6, lines 1-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the tubing (12) of Garay et al. with the catheter body having an embedded coil of Mouri et al. in order to allow the tubing to recoil to a smaller profile after inflation of the balloon to prevent damage to the inner wall of the stomach (col. 2, lines 29-34).

8. Regarding claims 11-13, Garay et al lack the teaching of that the retractable tubing is made of a material having a memory, a soft material comprising a radial spring, a semi-rigid material having a memory, and a shape memory alloy. However, Mouri et al. also teach that the catheter (11) may be formed from is formed of a soft

material (urethane, col. 5, line 53), a semi-rigid material (shape memory alloy, Col. 5, line 55), or a shape-memory alloy to return the tubing to the proper shape (shape memory alloy, col. 5, line 55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the tubing (12) of Garay et al. with the catheter body having an embedded coil of Mouri et al. in order to allow the tubing to recoil to a smaller profile after inflation of the balloon to prevent damage to the inner wall of the stomach (Mouri et al, col. 2, lines 29-34).

9. Claims 6-7, 14 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al in view of Gau et al, US Patent No. 5,084,061.

10. Regarding claims 6-7 and 14, Garay et al disclose the claimed invention except for a receiver that is a molded valve patch bonded to the shell. However, Gau et al. disclose an intragastric balloon (20), comprising a self sealing valve (28) and a valve cover patch (34, examiner also interprets this to be a cap) that is affixed to the exterior of the balloon shell using an adhesive (Col. 5, lines 34-36). The valve cover patch of Gau et al. has an "X" shaped slot (36) that is aligned with a hole (38) in the shell of the balloon for insertion of an inflation tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the valve patch system of Gau et al. to the receiver of Garay et al. in order to provide a barrier means at the surface of the balloon to prevent deflation of the balloon if the inflation tube were accidentally separated from the balloon.

11. Regarding claims 35-36, Garay et al disclose a gastric balloon (26) comprising: a shell (27); a valve (21) for preventing the undesired addition or elimination of fluid from the gastric balloon; a receiver (Portion of shell that receives tubing 12, see Fig. 5); and a retractable tubing (12) in said receiver and extendable from the stomach of a patient to the mouth of the patient (See Col. 3, lines 1-9), wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (Col, 3, lines 1-9). (See Fig. 5). Garay et al lack the teaching of a molded valve patch bonded to the shell. However, Gau et al. disclose an intragastric balloon (20), comprising a self sealing valve (28) and a valve cover patch (34, examiner also interprets this to be a cap) that is affixed to the exterior of the balloon shell using an adhesive (Col. 5, lines 34-36). The valve cover patch of Gau et al. has an "X" shaped slot (36) that is aligned with a hole (38) in the shell of the balloon for insertion of an inflation tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the valve patch system of Gau et al. to the receiver of Garay et al. in order to provide a barrier means at the surface of the balloon to prevent deflation of the balloon if the inflation tube were accidentally separated from the balloon.

12. Claims 8-9 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al in view of Cheng, US Patent No. 4,693,695.

13. Regarding claims 8 and 9, Garay et al disclose the claimed invention except that the receiver divides the shell substantially into two hemispheres and the tubing is wrapped around a small diameter portion of the shell. However, Cheng discloses a

balloon (12) having a receiver (42) which divides the balloon into two hemispheres (18/20) and houses a retractable tether (14) (Figs. 4-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the balloon of Garay et al. with two hemispheres connected by a receiver that provides fluid communication to both hemispheres as disclosed by Cheng, such that the retractable tubing (12) is in fluid communication with the receiver, in order to provide a means for decreasing the profile of the tubing once the gastric balloon reaches the gastric lumen.

14. Regarding claim 41, Garay et al disclose a gastric balloon (26) comprising: a shell (27); a receiver (Portion of shell that receives tubing 12, see Fig. 5); a valve (21) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (12) in said receiver and extendable from the stomach of a patient to the mouth of the patient (See Col. 3, lines 1-9), wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (Col, 3, lines 1-9). (See Fig. 5). Garay et al lack the teaching that the receiver divides the shell substantially into two hemispheres. However, Cheng discloses a balloon (12) having a receiver (42) which divides the balloon into two hemispheres (18/20) and houses a retractable tether (14) (Figs. 4-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the balloon of Garay et al. with two hemispheres connected by a receiver that provides fluid communication to both hemispheres as disclosed by Cheng, such that the retractable tubing (12) is in fluid communication with the receiver, in order to provide a means for decreasing the profile of the tubing once the gastric balloon reaches the gastric lumen.

15. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al in view of Adams, US Publication No. US 2002/0183765 A1.

16. Garay et al. disclose the claimed invention except for wherein said valve is a slit valve. However, Adams discloses a slit valve (104) contained in an inflation lumen (104) used to inflate a balloon (106). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the valve of Garay et al with the slit valve of Adams in order to permit passage of the balloon inflation fluid in one direction only (Adams, Para [0077]).

17. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al in view of Trick, US Patent No. 4,417,567.

18. Garay et al disclose the invention as claimed except wherein said valve is a septum. Trick discloses a balloon (18) having an elongated stem which is closed with a septum (24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the valve of Garay et al. with the septum of Trick in order to allow inflation fluid to be added to or removed from the inflation tube leading to the balloon by a hollow needle (Trick, Col. 2, lines 64-68, and Col. 3, lines 1-2).

19. Claims 15-18 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al in view of Duffy, US Publication No. 2005/0171568 A1.

20. Regarding claims 15-18, Garay et al disclose the invention as claimed except for a torsionally loaded axle, wherein said torsionally loaded axle resists removal of said retractable tubing from said receiver and returns said retractable tubing to said receiver for housing; wherein said torsionally loaded axle is located horizontally or vertically with respect to said receiver or wherein said torsionally loaded axle includes a pre-grooved surface for accommodating said retractable tubing.

21. However, Duffy teaches a torsionally loaded axle (26, Fig. 6), wherein the torsionally loaded axle resists removal of said retractable tubing from said receiver and returns said retractable tubing to said receiver for housing (paragraph 0032); and the torsionally loaded axle includes a pre-grooved surface (18, Fig. 6) for accommodating said retractable tubing. In the receiver of Garay et al as modified by Duffy, the torsionally loaded axle can be located horizontally or vertically with respect to said receiver. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the receiver of Garay et al such that the tubing (12) is accommodated by the wheel and the axle of Duffy in order to provide a means retract the tubing (12) into the receptacle of Garay et al, after the balloon is inflated (Duffy, paragraph 0032).

22. Regarding claims 37-40, Garay et al disclose a gastric balloon (26) comprising: a shell (27); a receiver formed in said shell (Portion of shell that receives tubing 12, see Fig. 5) having a recessed region in the shell (28, Fig. 5); a valve (21) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (12) in fluid communication with the shell house in said receiver and extendable

from the stomach of a patient to the mouth of the patient (See Col. 3, lines 1-9), wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (Col, 3, lines 1-9). (See Fig. 5). Garay et al lack the teaching of a torsionally loaded axle structured to retract said retractable tubing into the receiver, where the receiver has a longitudinal axis and the torsionally loaded axle is substantially aligned along the longitudinal axis or substantially perpendicular with the longitudinal axis.

23. However, Duffy teaches a torsionally loaded axle (26, Fig. 6), wherein the torsionally loaded axle resists removal of said retractable tubing from said receiver and returns said retractable tubing to said receiver for housing (paragraph 0032); and the torsionally loaded axle includes a pre-grooved surface (18, Fig. 6) for accommodating said retractable tubing. In the receiver of Garay et al as modified by Duffy, the torsionally loaded axle can be located along the longitudinal axis or substantially perpendicular to the axis of the receiver. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the receiver of Garay et al such that the tubing (12) is accommodated by the wheel and the axle of Duffy in order to provide a means retract the tubing (12) into the receptacle of Garay et al, after the balloon is inflated (Duffy, paragraph 0032).

Response to Arguments

24. Applicant's arguments filed December 10, 2010 have been fully considered but they are not persuasive. Applicant argues that Garay et al does not teach a receiver

having a recessed region in the shell and that the retractable tubing is housed in the receiver. However, Garay et al does teach a receiver (portion of shell that receives tubing, see Fig. 5) having a recessed portion (28) and where the retractable tubing is at least partially housing in the receiver as shown in Figure 5 (col. 5, lines 57-67).

25. Applicant argues that Cheng teaches away from Garay et al and is non-analogous art. In response to applicant's argument that Cheng is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Garay et al and Cheng are directed towards solving the problem of retaining a retractable tubing /tether in or around a balloon. In addition, Cheng does not teach away from Garay et al because the rejection states that it would have been obvious to modify the receiver of Garay with the receiver as taught by Cheng in order to retain the tubing in a retracted state to provide a means for decreasing the profile of the tubing once the gastric balloon reaches the gastric lumen. Cheng's teaching of a lighter-than-air gas is irrelevant to the problem of retaining the tubing around two hemispheres of a balloon.

26. Applicant also argues that neither Garay et al nor Gau teach a receiver having a molded valve patch. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642

F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Garay et al disclose a receiver and Gau teach a molded valve patch on a gastric balloon. The rejection in paragraphs 9-11 above states that it would have been obvious to modify the receiver as taught by Garay et al with the molded valve patch in the gastric balloon as taught by Gau in order to provide a barrier means at the surface of the balloon to prevent deflation of the balloon if the inflation tube were accidentally separated from the balloon.

27. In regards to Applicant's arguments with respect to claim 37 that neither Garay, Chen nor Ekich teach or suggest "a torsionally loaded axle structured to retract said retractable tubing into said receiver," the arguments have been considered but are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATRINA STRANSKY whose telephone number is (571) 270-3843. The examiner can normally be reached on Monday thru Friday, 8:00 am to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KS/
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3734
January 25, 2011